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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/519,388

03/17/2005

Helmut Schmidhammer

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2841

27799

7590

04/28/2006

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EXAMINER

AULAKH, CHARANJIT

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/519,388	SCHMIDHAMMER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Charanjit S. Aulakh	1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No.     .
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2</u> pages.  | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

1. According to a preliminary amendment filed on Feb. 9, 2005, the applicants have canceled claim 7 and furthermore, have amended claims 3, 5, 6, 8 and 10-14.
2. Claims 1-6 and 8-15 are now pending in the application.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pain, does not reasonably provide enablement for treating all other diseases such as rheumatic diseases, ileus, obstipation, overweight, addiction etc. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed: Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation

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necessary, the amount of direction or guidance provided, the state of the prior art, presence of working examples and the breadth of claims.

The instant specification demonstrates the analgesic effect of instant compounds as shown in tables 2-4 on pages 92-95. Based on these teachings, the instant compounds will have utility in treating pain. There is no teaching either in the specification or prior art references provided to show well known utility of structurally closely related compounds in treating rheumatic diseases, ileus, obstipation, overweight, addiction etc. There is no guidance or direction provided how the instant compounds having analgesic effect in an animal model will have therapeutic utility for treating all other diseases such as rheumatic diseases, ileus, obstipation, overweight, addiction etc. There are no working examples present showing efficacy of instant compounds in known animal models rheumatic diseases, ileus, obstipation, overweight, addiction etc. The instant compounds of formulae (I) , (Ia), (IA) and (IAa) encompass hundreds of thousands of compounds based on the values of variables R1-R5 and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in known animal models of rheumatic diseases, ileus, obstipation, overweight, addiction etc. and hence their utility for treating these conditions.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 1-5, 8, 9, 11 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 2, for the value of variable R4, line 1, something is missing after C1-C4.

Should it be C1-C4 alkyloxy?

In claims 1 and 2, for the value of variable R4, line 3, something is missing after C1-C6.

Should it be C1-C6 alkyl?

In claims 1 and 2, for the value of variable R4, line 4, something is missing after C2-C6 at two places. Should it be C2-C6 alkenyl and C2-C6 alkynyl?

In claims 1 and 2, for the value of variable R5, line 1, something is missing after C1-C4.

Should it be C1-C4 alkyloxy?

In claims 1 and 2, for the value of variable R5, line 3, something is missing after C1-C6.

Should it be C1-C6 alkyl?

In claims 1 and 2, for the value of variable R5, line 1 on pages 4 and line 4 on page 7, something is missing after C2-C6 at two places. Should it be C2-C6 alkenyl and C2-C6 alkynyl?

In claim 1, the term ---heterocyclical--- is vague. Should it be --heterocyclic---?

In claim 1, first proviso, last line, the term --when X is oxygen---- is not needed since X can only be oxygen.

In claim 1, last two provisos, the term --when R4 is oxygen ---- is indefinite since according to the definition of variable R4, It can not represent oxygen.

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In claims 3 and 4, the value of X is defined as oxygen. It is not needed since X is always oxygen.

In claim 3, line 3, something is missing after C3-C10. Should it be C3-C10 cycloalkyl?

In claim 3, line 3, something is missing after C1-C6. Should it be C1-C6 alkyl?

Claim 3 recites the limitation "C7-C16-arylalkyl for variable R2" in claim 1 or 2. There is insufficient antecedent basis for this limitation in the claim.

In claim 4, line 2, something is missing after C3-C10. Should it be C3-C10 cycloalkyl?

In claim 4, line 3, something is missing after C1-C6. Should it be C1-C6 alkyl?

In claim 5, the term ---easily accessible derivative of it--- is vague and indefinite since its meaning is not clear? Is there support for these derivatives in the specification?

In claim 8, the term ---obstipation--- is vague and indefinite since its meaning is not clear.

Claim 9 recites the limitation "alkoxy for variable R5" in claim 1 or 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "alkoxy for variable R4" in claim 1 or 2. There is insufficient antecedent basis for this limitation in the claim.

In claim 15, line 2, something is missing after C1-C6. Should it be C1-C6 alkyl?

In claim 15, line 3, something is missing after C2-C6. Should it be C2-C6 alkenyl?

In claim 15, line 4, something is missing after C2-C6. Should it be C2-C6 alkynyl?

Claim 8 provides for the use of a compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is

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intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Claim Rejections - 35 USC § 101***

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 8 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3, 5, 6, 8-10 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmidhammer ( Heterocycles, cited on applicants form 1449 ).

Schmidhammer discloses synthesis and biological evaluation of alkoxymorphinans. The compounds 9, 5 and 10 ( see scheme on page 491 ) disclosed by Schmidhammer anticipate the instant claims when R4 represents hydrogen in the instant compounds of formulae (I) and (Ia).

10. Claims 1, 3-6, 8, 10-12, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by compound, RN 139450-82-1 disclosed in 1991.

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The compound, RN 139450-82-1 anticipates the instant claims when R2 represents C2-C6-alkenyl in the instant compounds of formula (I).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625